

### REMARKS

The October 7, 2008 Official Action and the references cited therein have been carefully reviewed. In view of the amendments presented herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, Applicants note that the Examiner deemed the restriction requirement proper and has made it final. Accordingly, claims 3-6, 8, 9, 11, 12, and 15-30 have been withdrawn from consideration and claims 1, 2, 7, 10, 13, and 14 have been examined on the merits.

As another preliminary matter, the specification has been amended to remove the embedded hyperlink on page 25, thereby rendering the objection to the specification moot.

At page 4 of the Official Action, the Examiner has rejected claims 1, 2, 7, 10, 13, and 14 under 35 U.S.C. §102(b) as allegedly anticipated by O'Neill et al.

Claims 1, 2, 7, 10, 13, and 14 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Rovinski et al.

New claims 38-45 have been added with find support at pages 3 and 4 of the specification as filed.

Applicants respectfully submit that the claims as presently amended are in condition for allowance. Each of the above-noted rejections under 35 U.S.C. §102 is, therefore, respectfully traversed.

### **THE CLAIMS AS AMENDED ARE NOVEL OVER THE CITED PRIOR ART**

The present invention relates to a heterologous prime-boost immunization strategy where a lentivirus is used as a carrier of nucleic acid encoding the antigen of interest in either the priming phase or the boosting phase, but not both. The lentivirus expressing the antigen may be contained within an antigen presenting cell.

The application as filed (see pages 3 and 4) makes clear

that the antigen is an exogenous antigen. It further makes clear that the antigen may be a tumour associated antigen or a pathogen derived antigen, e.g. a viral antigen. In all cases, the application makes clear that such antigen is "engineered", e.g. by insertion into the lentivirus genome.

In order to support a rejection of claims under 35 U.S.C. §102, a reference must identically disclose each and every element of the claims. Applicants respectfully submit that the presently claimed method is not anticipated by the disclosures in either of the two cited prior art references.

O'Neill et al. disclose methods for developing vaccines against HIV. Specifically, the authors investigated an immunization strategy using a nucleic acid priming composition and a protein boosting composition. The priming composition used a pVecB7 plasmid which expressed a virus-like particle (VLP). The boosting composition also employed the VLP. Thus, the antigens were endogenous SIV-smH4 Gag, Rev, Env and Nef proteins. These were administered as DNA in the priming composition. The protein boost contained SIVsmB7 particles.

The authors also employed IL-12 as an adjuvant which was shown to provide improvement against SIV challenge in prime/boost immunized monkeys.

Rovinski et al. disclose the use of a prime/boost strategy to raise levels of antibody in a host against a primary HIV isolate. The priming composition comprises nucleic acid encoding the antigen (an envelope glycoprotein of a primary isolate of HIV-1). The boosting composition comprises a non-infectious, non-replicating HIV-like particle having the envelope glycoprotein of a primary isolate of HIV-1 or an attenuated viral vector expressing an envelope glycoprotein of a primary isolate of HIV-1. The attenuated viral vector is an avipox virus vector e.g. attenuated canary poxvirus AALVAC.

Notably, the immunisation strategy employs a prime/boost system for raising antibody against the endogenous env protein of a primary HIV-1 protein. The priming composition comprises nucleic acid encoding the env protein. This nucleic acid is

contained within a plasmid vector under the control of a cytomegalovirus promoter for expression within the host.

The boosting composition comprises the env protein from the primary HIV-1 isolate. This may be in the form of a modified HIV-like particle in that the LTRs are modified but the gag, pol and env are in their natural state, or the gag and pol genes are mutated to ensure attenuation.

While these references disclose the use of a lentivirus in the prime/boost immunization, the antigens employed are endogenous to the lentivirus. In contrast, in the presently claimed method the lentivirus is utilized as the vehicle adjuvant. In other words, the antigen has been "engineered" into the lentivirus genome.

In the case of O'Neill et al, the antigen was the whole lentivirus construct, i.e. the SIV-smH4 Gag, Rev, Env and Nef proteins. These were not "engineered" into the lentivirus itself and thus cannot be considered exogenous antigens.

Likewise with regard to Rovinski et al, the antigen was the env protein. Nucleic acid encoding this protein was "engineered" into a plasmid vector rather than a lentivirus vector such that its expression would be under the control of a cytomegalovirus vector. Thus, as with O'Neill et al., the antigen is not "engineered" into the lentivirus vehicle adjuvant.

Accordingly, neither O'Neill et al. nor Rovinski et al. disclose an identical method as in both cases, the antigen of interest is not engineered into a lentivirus.

In view of all the foregoing, it is clear that the presently claimed method is not anticipated by either of the references relied on by the Examiner. Accordingly, the rejections under 35 U.S.C. §102(b) are inappropriate and should be withdrawn.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned attorney at

the phone number given below.

Respectfully submitted,  
DANN, DORFMAN, HERRELL AND SKILLMAN  
A Professional Corporation

By:/Kathleen D. Rigaut/

Kathleen D. Rigaut, Ph.D., J.D.  
PTO Registration No. 43,047

Telephone Number (215) 563-4100